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| 10/698,555 | 10/31/2003 | Roland Christof Hutter | 21686-US | 9951 |
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| Roche Molecular Systems, Inc. Patent Law Department 4300 Hacienda Drive Pleasanton, CA 94588 | | | EXAMINER BOWERS, NATHAN ANDREW | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,555

Applicant(s)

HUTTER ET AL.

Examiner

NATHAN A. BOWERS

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) _____ is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 1) Claims 9-13 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lehmann (US 1161984).

With respect to claim 9, Tanaami discloses a reaction vessel for processing a biological sample. The reaction vessel comprises a tubular body (Figure 5:12) having a bottom wall, an upper opening and sidewalls. The bottom walls and sidewalls form a

straight tubular chamber for receiving a liquid and for interacting with a pipetting tip.

Paragraphs [0026]-[0029] state that the pipetting tip (Figure 6:18) can be pushed through a rubber plug (Figure 6:13) that seals the top opening of the tube. A chip shaped carrier (Figure 5:16) having an active surface formed by a plurality of biopolymers (Figure 5:CL21-CL23) is located on the inner surface of the tubular sidewall. This is disclosed in paragraphs [0024]-[0026]. Tanaami, however, does not expressly state that the chip shaped carrier is located in either an opening of a tube side wall or in a recess formed within the inner surface of a tube side wall.

Lehmann discloses a reaction vessel for processing a biological sample contained in a liquid. The vessel includes a body (Figure 1:15) having a bottom wall, an upper opening (Figure 1:13), and sidewalls which extend between the bottom wall and the upper opening. The bottom wall and the sidewalls form a chamber (Figure 5:33) for receiving a liquid to be processed. A chip shaped carrier (Figure 2:21) having an active surface (Figure 2:32) is accessible to liquid contained in the chamber. The chip shaped carrier is located in an opening (Figure 2:18) in the sidewall of the tubular body. This is disclosed in paragraphs [0021]-[0025], [0032] and [0033].

Tanaami and Lehmann are analogous art because they are from the same field of endeavor regarding biological sample processing reaction vessels that comprise an internal chip shaped carrier.

At the time of the invention, it would have been obvious to provide the chip shaped carrier disclosed by Tanaami either within an opening of the tube side wall or within a recess formed in the interior surface of the tube side wall. As evidenced by

Lehmann, this configuration is considered to be well known in the art. Paragraphs [0044]-[0047] state that the positioning of a biochip within the side wall surface of a reaction vessel can be carried out using known techniques quickly and easily using an automated instruments. Placement of the Tanaami chip within an opening or depression formed within a side wall would require only a minor structural alteration, that, as evidenced by Lehmann, would be completed in a highly predictable manner.

With respect to claim 10, Tanaami and Lehmann disclose the reaction vessel in claim 9 wherein the tubular body is configured and dimensioned such that, when the chip shaped carrier is contacted with a liquid, an air space exists between the free surface of the liquid and the upper opening. Although Tanaami does not clearly describe these limitations, the disclosed device is configured and dimensioned in such a way that it is capable of fulfilling these requirements. This is apparent from Figure 5.

With respect to claim 11, Tanaami and Lehmann disclose the reaction vessel in claim 9 wherein the chip shaped carrier is located at a predetermined distance from the bottom wall and from the upper opening of the tubular body.

With respect to claims 12 and 13, Tanaami and Lehmann disclose the reaction vessel in claim 9 wherein the chip shaped carrier is transparent. In paragraph [0030], Tanaami teaches that the biopolymers immobilized upon the carrier are optically evaluated using a light source and a detector. Figure 5 indicates that the excitation light

and emission light are moved through the body of the carrier, as well as through the sidewall of the tubular chamber.

With respect to claims 22 and 23, Tanaami and Lehmann disclose the reaction vessel in claim 9. Tanaami further states that the vessel further comprises a cap (figure 5:13) for removably closing the opening. The rubber plug cap is configured and dimensioned such that a part thereof may cooperate with the gripper of a transport mechanism.

With respect to claim 24, Tanaami and Lehmann disclose the reaction vessel in claim 9. The only opening disclosed by Tanaami is the upper opening of the tubular body.

With respect to claims 17, 18, 20 and 21, Tanaami and Lehmann disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not provide specific dimensions describing the volume of the reaction chamber or the shape of the carrier chip. Regardless, it would have been obvious to ensure that the chamber had a width of at least 1.5 mm and an inner volume of 10-800 microliters if it was determined that these dimensions produced the most effective results. Reaction chamber side lengths are considered result effective variables that are optimized through routine experimentation. Furthermore, it would have been obvious to ensure that the carrier chip had a side length between 2 to 10 mm. A chip of these dimensions

would be large enough to be easily micromachined using known techniques, but small enough to fit within a common test tube. At the time of the invention, it would have been apparent to fashion the reaction chamber disclosed by Tanaami according to the specifications presented in claims 17, 18, 20 and 21 if it was determined that these measurements allowed the device to function at an optimum level.

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lehmann (US 1161984) and Lary (US 4845025).

Tanaami and Lehmann disclose the combination as previously described above, however, do not expressly indicate that the vessel is in communication with a vessel holder capable of moving along a predetermined elliptical trajectory.

Lary discloses a system from processing a test tube (Figure 15:24) in which a reaction vessel is coupled to a vessel holder in the form of a mixing arm (Figure 15:52). Figures 15 and 16 and column 7, line 59 to column 8, line 13 state that the mixing arm is moved along a predetermined elliptical trajectory for causing mixing of fluids within the vessel.

Lehmann and Lary are analogous art because they are from the same field of endeavor regarding reaction vessels.

At the time of the invention, it would have been obvious to utilize a moving means such as described by Lary to influence mixing within the reaction vessel disclosed by Tanaami. It is well established in the art that mixing means are beneficial because they allow one to provide effective contact between the sample solution and

the active surface of the chip shaped carrier. The specific mixing mechanism of Lary is advantageous because it is highly reproducible, inexpensive, and more reliable than other mixing devices that are based on liquid circulation via pumping.

3) Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lehmann (US 1161984) and Lary (US 4845025) as applied to claim 5, and further in view of Frackleton (US 5133937).

Tanaami, Lehmann and Lary disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

Tanaami and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to incorporate heat transfer elements in the system disclosed by Tanaami. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

4) Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lehmann (US 1161984) as applied to claim 9, and further in view of Frackleton (US 5133937).

Tanaami and Lehmann disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

At the time of the invention, it would have been obvious to ensure that the device disclosed by Tanaami was capable of interacting with various heat transfer elements. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

5) Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lehmann (US 1161984) as applied to claim 9, and further in view of Mochida (GB 2129551).

Tanaami and Lehmann disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly indicate that the sidewalls carry a barcode label.

Mochida discloses the use of immunoassay vessels (Figure 1:1) that utilize barcode labels (Figure 1:2) as a tracking mechanism. This is disclosed on page 3, lines 60-64.

Tanaami and Mochida are analogous art because they are from the same field of endeavor regarding biological analysis devices.

At the time of the invention, it would have been obvious to include a bar code label on the outer sidewalls of the reaction vessel disclosed by Tanaami. Bar codes are helpful in quickly sorting and tracking reaction vessels, and they can be used to immediately determine the identity of a specified reaction vessel in the presence of a plurality of otherwise identical reaction vessels, thus reducing confusion and the occurrence of mistakes.

Response to Arguments

In response to Applicant's amendments, all previously applied rejections under 35 U.S.C. 112 second paragraph have been withdrawn.

Applicant's arguments filed 25 November 2008 with respect to the 35 U.S.C. 102 rejections involving Tanaami have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration,

a new ground of rejection is made in view of the combination of Tanaami and Lehmann and the combination of Tanaami, Lehmann and Lary.

Applicant's principle arguments are

(a) Tanaami does not disclose that the chip shaped carrier is located in an opening of a side wall of the tubular body or in a recess formed in the inner surface of the side wall.

In response, please consider the following remarks.

As noted above, it would have been obvious to position the chip shaped carrier of Tanaami within an opening or recess formed in a side wall in light of the teachings of Lehmann. Lehmann discloses effective procedures for positioning a biological analysis chip within the side wall of a surrounding reaction vessel.

(b) Tanaami does not disclose that the device is designed to receive a pipetting tip.

In response, please consider the following remarks.

Tanaami states in paragraphs [0026]-[0029] that a pipetting tip (Figure 6:18) can be pushed through a rubber plug (Figure 6:13) that seals the top opening of the tube.

Furthermore, Lehmann expressly states in paragraph [0021] that an unoccluded opening (Figure 1:13) is provided for introducing a solution into the reaction vessel. Assuming for the sake of argument that it is impossible for a pipetting tip to penetrate the rubber plug of Tanaami, one of ordinary skill in the art would have found it obvious to substitute the fluid introduction system disclosed by Tanaami with the fluid

introduction system set forth by Lehmann. More specifically, one of ordinary skill in the art would have recognized that the fluid introduction means set forth by Tanaami and Lehmann are functional equivalent, and that it would have been obvious to replace the Tanaami plug with the unblocked orifice of Lehmann.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797